Citation:

Dhingra R, Sullivan L, Jacques PF, Wang TJ, Fox CS, Meigs JB, D'Agostino RB, Gaziano JM, Vasan RS. Soft drink consumption and risk of developing cardiometabolic risk factors and the metabolic syndrome in middle-aged adults in the community. *Circulation*. 2007 Jul 31;116(5):480-8.

PubMed ID: 17646581

Study Design:

Prospective Cohort Study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the relationship between the incidence of metabolic syndrome and its components to soft drink consumption in participants in the Framingham Heart Study. Additionally, it was evaluated whether metabolic risk varied on the basis of consumption of sugar-sweetened ("regular") versus artificially sweetened ("diet") soft drinks.

Inclusion Criteria:

Framingham Offspring Study participants that attended any 2 consecutive examinations from the fourth through the seventh (1998-2001) examination cycles.

Exclusion Criteria:

Participants with missing data on covariates, those with prevalent cardiovascular disease, those with baseline metabolic syndrome and those with any missing metabolic syndrome components on follow-up.

Description of Study Protocol:

Recruitment: Participants from the Framingham Offspring Study

Design: Prospective cohort study

Blinding used: not applicable

Intervention: not applicable

Statistical Analysis:

- Multiple regression was used to test for trend in baseline characteristics across soft drink consumption categories
- Multivariate models were used to adjust for age, sex, physical activity index, smoking, dietary consumption of saturated fat, trans fat, fiber, magnesium, total calories and glycemic index
- Logistic regression was used to relate number of soft drinks consumed per day to the incidence of metabolic syndrome
- Multivariate logistic regression was used to evaluate the relations of soft drink consumption to the incidence of each individual component of metabolic syndrome using data from the examination cola questionnaire.

Data Collection Summary:

Timing of Measurements:

- At each Framingham Heart Study examination, participants provided a medical history and underwent a complete standardized physical examination that included anthropometry, blood pressure measurements and laboratory assessment of vascular risk factors.

Dependent Variables

- Risk of metabolic syndrome
  - Fasting levels of blood glucose, triglycerides and HDL-C were measured with standard assays
  - Anthropometrics were measured by study personnel

Independent Variables

- Soft drink consumption: Information on daily consumption of soft drinks was collected via a physician-administered questionnaire at each study visit from the fourth (1987–1991) through the sixth (1995–1998) examination cycles. Participants reported the average number of 12-oz svgs of soft drinks consumed per day in the yr preceding the examination. The examination questionnaire did not elicit information regarding consumption of regular versus diet soft drinks; however, such information was available from the self-administered FFQ completed by participants at the fifth (1992–1995) and sixth examination cycles. Individuals were categorized as consuming <1, 1, ≥1, or ≥2 soft drinks per day.

Control Variables

- Race
- Age
- Sex
- Physical activity index
- Smoking
- Dietary consumption of saturated fat, trans fat, fiber, magnesium, total calories and glycemic index

Description of Actual Data Sample:

Initial N: 8997 participants (4126 men and 4871 women)

Attrition (final N): 6039 participants (2569 men and 3470 women)

Age:

- Participants drinking <1 soft drink/day: 56±10 years
- Participants drinking 1 soft drink/day: 53±10 years
- Participants drinking ≥2 soft drinks/day: 51±9 years

Ethnicity: White

Other relevant demographics:

Anthropometrics:

	Number of soft drinks consumed per day			
Characteristic	<1 (n=5840)	1 (n=1918)	≥2 (n=1239)	*P*
BMI, kg/m^2	26.8±4.8	27.8±5.1	28.5±5.4	<0.0001
BMI ≥30 kg/m^2, %	20.9	27.1	32.1	<0.0001

Location: United States

Summary of Results:

Key Findings

- Approximately 35% of the participants reported consuming ≥1 soft drink per day in response to the examination cola questionnaire (data based on all 3 examinations)
- In comparison, only 22% of participants reported intake of at least 1 soft drink (diet or regular) per day in response to the FFQ
- In age- and sex- adjusted models, the prevalence of obesity, high blood pressure, glucose intolerance, low HDL-C, and hypertriglyceridemia was significantly higher in those who consumed a greater number of soft drinks per day
- Over a mean follow-up of 4 yrs, consumption of ≥ 1 soft drink (including regular and diet) per day was associated with increased odds of developing obesity (multivariable adjusted OR = 1.31; 95% CI: 1.02, 1.68) and increased waist circumference (multivariable adjusted OR = 1.30; 95% CI: 1.09 to 1.56) compared to drinking none.
- Serum total cholesterol, low-density lipoprotein cholesterol, physical activity index and alcohol consumption did not vary across categories of soft drinks consumed
- There was a 48% higher adjusted prevalence of metabolic syndrome among those who consumed 1 or more soft drinks per day relative to individuals with infrequent soft drink consumption
- A rising prevalence of metabolic syndrome across categories of 1 and ≥2 soft drinks per day was observed
- In parallel analyses with the data from the FFQ, participants who consumed ≥1 diet or regular soft drinks per day had nearly a 1.8-fold adjusted prevalence of metabolic syndrome compared with infrequent drinkers (<1 per week)
- Individuals who consumed at least 1 soft drink per day had a 44% higher adjusted risk (95% CI, 20% to 74%) of developing metabolic syndrome compared with infrequent drinkers in multivariable-adjusted analyses

- After additional adjustment for baseline levels of covariates (blood sugar, systolic and diastolic blood pressure, triglycerides and HDL-C) and alcohol consumption in out models, the association of consumption of ≥1 soft drinks per day with incidence of metabolic syndrome remained robust (odds ratio [OR], 1.44: 95% CI, 1.19 to 1.74)
- After stratification of analyses by caffeinated versus decaffeinated drinks, results were consistent with the primary analyses; consumption of ≥1 soft drink per day was associated with incident metabolic syndrome for both types of beverages
- In analyses with FFQ data, intake of at least 1 regular or diet soft drink per day was associated with a >50% higher incidence of metabolic syndrome than among those who drank <1 soft drink per week, although the association was borderline significant for intake of ≥1 regular soft drink per day (*P*=0.07)
- A graded increase in the risk of metabolic syndrome from those who were consuming 1 to 6 diet or regular soft drinks per week to those who drank ≥1 soft drinks per day (diet or regular) was observed
- Compared with infrequent drinkers, individuals who consumed ≥1 soft drink per day had a 25% to 32% higher adjusted risk of incidence of each individual metabolic trait with the exception of development of high blood pressure, for which there was a borderline significant 18% higher adjusted odds (*P*=0.10).

Author Conclusion:

- A significantly higher prevalence of metabolic syndrome among middle-aged adults who consumed ≥1 soft drink per day was observed. This association was consistent for intake of both regular and diet soft drinks
- Consumption of soft drinks daily was associated with a higher incidence of each metabolic syndrome component
- Saturated fat and trans fat intake, dietary fiber consumption, smoking and physical activity were adjusted in multivariate analyses and still observed a significant association of soft drink consumption with the risk of developing metabolic syndrome and its component traits.

Reviewer Comments:

- *The modified definition of metabolic syndrome recommended by the National Cholesterol Education Program was used instead of other criteria for the syndrome (such as suggested by the World Health Organization or the European Panel)*
- *It is conceivable that residual confounding by lifestyle/dietary factors not adjusted for may have contributed to the metabolic risks associated with soft drink intake*
- *Participants in the present study were all white Americans, which may limit the generalizability of the results.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	N/A

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	Yes
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	N/A

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes